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A Look into the Economics behind Cancer Interventions and Drug Development

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Abstract

Cancer is an extraordinarily tough combatant and is quickly becoming the number one cause of death in the world. With the global economic cost of cancer accumulating to $1.16 trillion in 2010, something has to be done to decrease this financial and societal weight that's suffocating humanity. Through cost-effective analysis, it was found that cervical cancer interventions were the most cost-effective given their inclusion of advantageous preventative strategies at low costs. By implementing preventative measures, using a step-wise approach to treatment as dictated by the expansion path, and intervening at the earliest stages of cancer provide the most cost-effective outcomes. With revenues for pharmaceutical companies exceeding their research and development costs by potentially ten-fold only adds fuel to the fire on the drug pricing debate. Through cost-effective treatment of cancer and increased competition amongst pharmaceutical firms developing oncologic drugs to lower prices and increase patient access, the burden of cancer can begin to shrink.

Keywords: Cancer, Drug Development, Immune system, Tumor.

Abbreviations: PURE- Prospective Urban and Rural Epidemiologic, WHO-World Health Organization, HLY-Healthy Life Years, HPV- Human PapillomaVirus.

Introduction

The threat to life that is cancer has shown to be a formidable foe to society like nothing ever before it and recent studies have shown and confirmed the genuine deadly nature of cancer. A 2017 PURE study found that amongst high-income countries, cancer was the number one killer ahead of cardiovascular disease [1]. Globally, heart disease remains the leading cause of death amongst middle-aged adults accounting for 40% of all deaths, and cancer accounting for roughly 26% in second place [1].

However, in wealthy countries this landscape is quickly changing as cancer is now taking the lives of close to twice as many people as heart disease, potentially due to a shift seen in wealthier countries because of better healthcare that can control heart disease more effectively. Cardiovascular disease can be treated with cholesterol-lowering drugs, blood pressure medications can be prescribed, and so on.

The high rates of cardiovascular disease in lower-income countries are most likely due to a lack of quality healthcare to properly treat the disease [2]. The study by PURE goes on to predict that as heart disease treatment in poorer countries improves, a change in the leading cause of mortality worldwide from cardiovascular disease to cancer is very much possible. The point being that cancer is on the rise and is already a challenging adversary where treatments are needed to be effective both biologically and economically.

Although this paper is not of an original analysis that features original data, it still provides valuable insight into the economic mechanisms of cancer treatment. This paper is a review study of existing data along with our own opinions. The gathering of this data all in one paper allows for the reader to garner the knowledge of the economics of various cancer treatments and the development behind them without having to undergo an extensive researching expedition.

The information can be readily obtained upon reading. The data gathered is also still very much pertinent to today's cancer climate as breast and colorectal cancer are amongst the top three most common cancers in the world across both sexes, and cervical cancer is the fourth most common amongst women [3].

The cost-effective analysis executed by Ralaidovy et al. [4] illustrates the most cost-effective treatment routes across breast, colorectal, and cervical cancers, whereas Prasad and Mailankody [5] and Tay-Teo et al. [6] look at the research and development costs of cancer drugs as well as the accumulation of profits for pharmaceutical companies.

The Impact of Cancer

Cancer care costs in Canada have risen steadily from $2.9 billion in 2005 to $7.5 billion in 2012 as seen in a population-based cost study [7]. With this increasing financial burden mounting, it is important to come up with solutions to manage this cost. As Dr. Gary Lyman explains, a higher cost is acceptable if it means a better clinical outcome [8]. But if clinical outcomes are the same, it is useful to implement the treatment that has the lowest cost. Cancer is a deadly disease that needs to be reined in so that all of the costs associated with it can be reduced. The costs of the medical care being given, the costs of missing work if one is the patient or caregiver and the pain of losing a loved one that is much too often associated with cancer need to be decreased [8].

In analyzing innovative and breakthrough cancer treatments, one has to look at the costs and benefits associated with the therapy. A recent breakthrough in cancer treatment has been using bacteria to either activate the immune system to attack the tumour site, or to couple the bacteria treatment with a conventional cancer treatment to attack the tumour site. However, from an economics standpoint, if the clinical trials are not successful or the treatment is not something that is desperately needed for individuals coping with cancer, then pharmaceutical companies will not develop it. The cost of development outweighs the costs of creating a treatment that could potentially work on patients.

This is what cancer treatment developers are trying to do; minimize the costs while creating a therapy that works extremely well. This is very difficult to do. Cancer is a danger that everyone is trying to neutralize and to do so requires some clever research while also not emptying the pockets of every pharmaceutical company or family paying for the treatment. The cost of an effective treatment should never be an issue for a patient, but it sadly is. A positive patient outcome is what is most desired by both the development company to ensure returns on their investment and by the patient to increase their years of life, yet a balance between the benefits and costs of treatment must be reached.

As eluded to, cancer is one of the greatest dangers to life out there and is a worldwide source of disease and mortality. It's caused such strife that it is now a global issue featured in the sustainable development goals agreed upon by the United Nations Member States in 2015. This target's objective is to by 2030 decrease premature death as a result of non-communicable diseases by one third [4]. The idea behind these goals is to have a laid-out roadmap for peace and for overall well-being for the people of our planet [9].

Cancer is responsible for at least 1 in 6 deaths worldwide and the greatest increase in death due to cancer has been in low and middle-income countries where their healthcare systems are the least equipped to treat such an adversary [4,10]. Deaths due to cancer are increasing in areas of Asia and Africa and among sub-Saharan Africa; cervical and breast cancer is the most destructive in terms of deaths of women due to cancer in the region, responsible for 23.2% (cervical) and 19.3% (breast) of all cancer deaths [4]. Whereas, across the globe and over both sexes, colorectal cancer is one of the most prominent culprits of cancer-related deaths [11].

In 2010, the global economic cost of cancer was around US$ 1.16 trillion. In the U.S. alone for 2015, the total health care costs for cancer were $80.2 billion [12]. These extreme costs are not only a problem for a country's economy, but also for the individual family that has to take on the financial burden of paying for the treatment. Aligned with the sustainable development goals initiated by the UN is the Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020 [4].

A potential solution to tackle this problem in respect to the global initiatives is to increase the efficiency and accessibility of screening programs for cancer, especially in Southeast Asia and eastern sub-Saharan Africa. These regions were found to be the least probable in comparison to other WHO regions to have a breast screening program for breast cancer with 64% in Southeast Asia and 57% availability in Africa regions; cancer centres/departments were also found to be infrequently available with 55% of countries in Southeast Asia to have them and 30% in the Africa regions. Treatment for cancer was also found to be lacking in the majority of the countries in these regions and of note is that in the majority of these countries any HPV vaccine available to prevent cervical cancer reaches less than 10% population coverage [4].

Cost-Effective Analysis in Southeast Asia and sub-Saharan Africa Paper Review

Ralaidovy et al. used Generalized Cost-Effectiveness Analysis and data specific to the Southeast Asia and sub-Saharan Africa regions in order to study and identify the most cost-effective treatments related to breast, cervical, and colorectal cancer [4]. This analysis was used in Southeast Asia and eastern sub-Saharan Africa given their distinct geographic and epidemiologic make-up.

The analysis emphasized interventions that were pertinent to a comprehensive cancer control program. This program basically looks at the most efficient and practical ways to treat cancer as it looks at prevention, early diagnosis and screening, a multi-modality method of treatment, and survivorship. Using this comprehensive approach allows for an emphasis on the characteristics of cancer care that are generalizable to all regions regardless of resource supply. Using this approach has also been linked to establishing more cost-effective treatments.

The investigators looked at the expansion path when analyzing their interventions, thus looking at interventions that provide an optimal outcome based on healthy life years gained and the associated cost [4]. If a type of technology appeared on this expansion path for a given coverage level, then the most cost-effective treatments including this technology would be considered at this level of coverage and higher. **Figure 1** shows the expansion path for Southeast Asia.

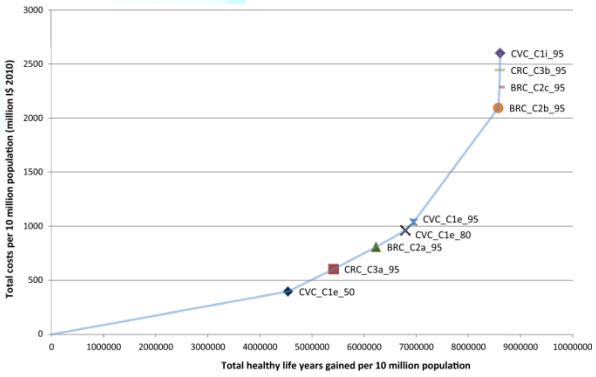

Figure 1: The cost-effectiveness expansion path of various interventions for Southeast Asia [4].

This type of analysis ensures that this technology is useful for greater levels of coverage and prevents the inefficient practice of having to replace this technology with a different one on the expansion path as coverage increases. Health outcomes were measured as the gain in HLYs when compared to no intervention and were approximated using a deterministic state-transition cohort simulation model (Markov model) in the Spectrum software.

Markov model looked at healthy stages and disease stages and the transition between the two was measured in regard to the interventions. For example, the model applies a higher rate/value when a transition to a more severe stage of disease occurs which indicates the lack of efficacy of the treatment [4]. Or when looking at the rates going from a healthy state to an HPV one, the transition rates are lower given the efficacy **(Table 1)**.

A sampling of the interventions that were analyzed are in Table 1 and are based on WHO guidelines that emphasize the comprehensive cancer control approach [4]. Each intervention was assessed at 50%, 80%, and 95% coverage levels of the population. Cervical cancer often has its foundation laid in HPV and is why it was a focus in this analysis **(Tables 2and 3)**.

Disease	Label	Interventions
Cervical cancer	C1a	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls
	C1e	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls and prevention of cervical cancer by screening women aged 30–49 through visual inspection with acetic acid linked with timely treatment of pre-cancerous lesions
	C1f	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls and prevention of cervical cancer by screening women aged 30–49 through Pap smear (cervical cytology) every 3–5 years linked with timely treatment of pre-cancerous lesions
	C1h	Treatment of cervical cancer stages I and II with either surgery or radiotherapy ± chemotherapy
Breast cancer	C2a	Treatment of breast cancer stages I and II with surgery ± systemic therapy
	C2b	Screening with mammography (once every 2 years for women aged 50–69 years) linked with timely diagnosis and treatment of breast cancer
Colorectal cancer	C3a	Treatment of colorectal cancer stages I and II with surgery ± chemotherapy and radiotherapy

Table 1: A Sample of the Interventions that were looked at in the analysis [4].

Label	Description of the intervention	Pop° coverage (%)	Costs per 10 million population (million I$ 2010)	HLY per 10 million population (undiscounted)	Average cost-effectiveness ratio (ACER)	Incremental cost-effectiveness ratio (ICER)
CVC_C1e	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls and prevention of cervical cancer by screening women aged 30–49 through visual inspection with acetic acid linked with timely treatment of pre-cancerous lesions	50	396	4,541,842	87	87
CVC_C1e	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls and prevention of cervical cancer by screening women aged 30–49 through visual inspection with acetic acid linked with timely treatment of pre-cancerous lesions	95	626	5,262,580	119	491
BRC_C2a	Treatment of breast cancer stages I and II with surgery ± systemic therapy	95	206	816,200	252	252
BRC_C2b	Screening with mammography (once every 2 years for women aged 50–69 years) linked with timely diagnosis and treatment of breast cancer	95	1056	1,627,782	649	1048
CRC_C3a	Treatment of colorectal cancer stages I and II with surgery ± chemotherapy and radiotherapy	95	207	870,417	238	238

CVC = cervical cancer, BRC = breast cancer, CRC = colorectal cancer

Table 2: Cost-effectiveness and HLYs gained at various coverage points of the most cost-effective cancers analyzed, in Southeast Asia [4].

Label	Description of the intervention	Pop° coverage (%)	Costs per 10 million population (I$ 2010)	HLY per 10 million population (undiscounted)	Average cost-effectiveness ratio (ACER)	Incremental cost-effectiveness ratio (ICER)
CVC_C1a	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls	50	146	5,215,136	28	28
BRC_C2a	Treatment of breast cancer stages I and II with surgery ± systemic therapy	95	157	1,389,662	113	113
CVC_C1e	Vaccination against human papillomavirus (two doses) of 9–13-year-old girls and prevention of cervical cancer by screening women aged 30–49 through visual inspection with acetic acid linked with timely treatment of pre-cancerous lesions	95	1362	31,554,286	43	175
CRC_C3a	Treatment of colorectal cancer stages I and II with surgery ± chemotherapy and radiotherapy	95	136	626,379	217	217
BRC_C2b	Screening with mammography (once every 2 years for women aged 50–69 years) linked with timely diagnosis and treatment of breast cancer	95	1307	2,697,617	485	485

Table 3: Cost-effectiveness and HLYs gained at various coverage points of the most cost-effective cancers analyzed, in Sub-Saharan Africa [4].

Tables 2 and 3 show the costs, the healthy life years gained, and the cost-effectiveness of the most cost-effective treatments from being on the expansion. Regarding cervical cancer, it was found that vaccinating young girls of ages 9-13 against HPV and combining this with screening tests of cervical cancer for women aged 30-49 in conjunction with timely treatment of pre-cancerous lesions at 50% coverage (CVC_C1e, Table 2) was the most cost-effective course of action in Southeast Asia given its low ICER and ACER cost per additional healthy life year gained. This intervention becomes the most effective of all cervical cancer treatments when the coverage is increased to 95% of the population; the HLYs gained are the greatest.

In sub-Saharan Africa, this same vaccination treatment at 50% coverage (CVC_C1a, Table 3) was the most cost-effective cervical cancer intervention with an ICER cost of $28 per HLY gained. To then promote continued prevention and maximize HLYs gained, combining this intervention with screening of 30-49 year-old women along with opportune treating of pre-cancerous lesions at 95% coverage will do the trick and results in a large number of HLYs gained (CVC_C1e, Table 3).

When looking at breast cancer interventions, treating stages I and II with surgery and/or conventional cancer therapy with a 95% coverage level (BRC_C2a, Tables 2 and 3) proved to be the most cost-effective with low ICERs per HLY gained in both regions. The intervention involving screening with mammography (BRC_C2b) was less cost-effective given that this technology requires significant resources and needs substantial health infrastructure to be a successful screening program. Turning to colorectal cancer, the intervention of using surgery and/or the conventional cancer therapies of chemotherapy and radiotherapy to treat stages I and II with 95% coverage was the most cost-effective in both regions (CRC_C3a, Tables 2 and 3).

In reviewing all of the cost-effective cancer treatments, cervical cancer appears to have the most cost-effective treatment regimens given its impactful preventative strategies at low costs. Some of the keys of what Ralaidovy et al. [4] found was that cancer prevention methods (such as vaccines) are cost-effective and are thus able to decrease the burden of the cancer, a step-wise course of action is of value in targeting the early stages of cancer with treatment before moving on to screening programs as seen by following the expansion path, and interventions at the earliest stages of cancer were more cost-effective than interventions on later-stage cancers [4].

In developing countries, the resource allocation to cancer care is often low, reflecting the pre-conceived notion of high costs and low health impact of the interventions [4]. But the cost-effectiveness of several of these interventions begs to differ.

Regarding this step-wise approach when looking at breast cancer for example, in following the expansion path (Figure 1), the treating of breast cancer at its earliest stages was found to be more cost-effective than the intervention of screening via mammography as seen from its placement on the expansion path and due to the ICER values of $252 vs $1048 per HLY gained (Table 2) [4]. This step-wise approach thus emphasizes the increased availability of cancer treatments before progressing to screening at a population or community level.

The first step would be this treatment of the early stages, and then the next step would be a progression to the screening program. This idea of diagnosing cancer at its most infant stages was often associated with a less expensive treatment. Treatment for colorectal cancer at stage I was about five times cheaper than treatment for colorectal cancer at stage II, and a greater effect of the treatment is felt as well when intervening at stage I. Having strategies of diagnosing cancer early would allow for better control of cancer and a more cost-effective outcome given treatment options are more effective and cheaper when treating these earlier stages.

Research and Development Costs

On a different note, the research and development aspect of cancer is also very fascinating. The background behind the drugs that one takes to fight this disease that is taking hold of their life and the money behind it all. What Prasad et al. [5] found was that the median cost of developing a single cancer drug in 2017 US dollars was $648 million, in a range of $157 million to $1.9 billion [5]. This monetary value is quite large, but not as large as the $2.7 billion that has been published in other literature.

Accounting for a 7% per year opportunity cost, the median cost rose to $757 million [5]. They looked at ten drug companies who developed a single drug over a median period of 7.3 years (between 6-15 years). From the onset of drug approval by the FDA until December 2016, the ten drug companies had made a combined $67 billion over a median of four years since approval by the FDA. For each of the companies, their median revenue was $1.7 billion, over a range of $204 million to $22.3 billion. Of the ten drug companies and their drugs that were studied, nine of the drugs had greater revenues than their expenditures put into research and development, and four (ponatinib, ibrutinib, enzalutamide, and eculizumab) of the ten drugs had revenues more than ten times greater than their research and development costs **(Figure 2)**.

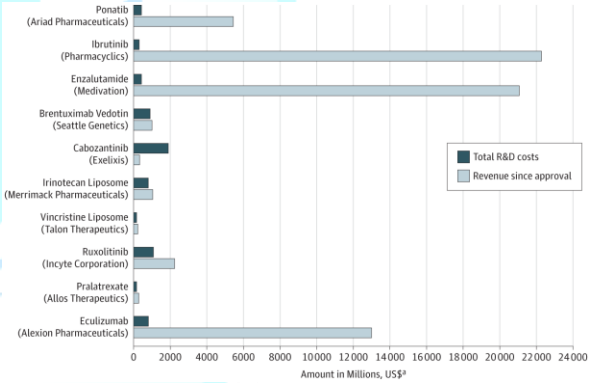

Figure 2: Total Research and Development Costs compared to the revenue gained after drug approval for each of the 10 drug companies [5].

Figure 2 highlights these cost and revenue relationships amongst drug companies. Overall, total expenditures to develop the drugs from all of the ten companies combined was $9 billion and with the total revenue being $67 billion, the revenue that these companies have gained is more than seven times greater than their research and development costs [5]. These results only fuel the debate even further regarding the pricing of cancer drugs and warrant even further transparency by pharmaceutical companies in order to understand if there is a reason as to why these drugs are costing so much and to create effective policy surrounding these drugs.

Other studies have illustrated the obscene amount of money that cancer drug developers are making. The median income returns for 99 cancer drugs with FDA approval from 1989 to 2017 was $14.50 for every dollar of research and development expenditures [6]. 33 drugs have already been given the recognition as "blockbuster drugs" for having average annual sales greater than $1 billion. These high drug prices are enabling the accumulation of income for pharmaceutical companies far greater than their R&D costs. These high profits would not be of such concern if the drugs were affordable and thus accessible to cancer patients.

However, this is most certainly not the case. The worldwide access to cancer drugs remains low and due to these high prices, insurance companies are excluding patients from coverage as the costs are just too much to bear. Patient access needs to be improved by encouraging competition and lowering prices of these drugs. An adverse response to these high returns from cancer drug development is that pharmaceutical companies are committing so much to R&D for cancer drugs that potential research for other diseases takes a back seat.

Conclusion

For a family experiencing the hardships of cancer, having effective treatments being affordable is an absolute must. Having the peace of mind in knowing that you have a treatment that can do its job and put some money back in your pocket is what families need to have. They are already being put through enough, the least they could have is a cost-effective treatment.

By taking on preventative measures such as vaccination, one can put themselves one step ahead and help decrease the toll of this disease around the world. Also using a step-wise approach and intervening via treatment in the earliest stages of cancer, patients will achieve the most cost-effective outcomes. In conjunction with cost-effective treatments to fight and prevent cancer, reasonable drug prices are a must. There either seems to be a lack of transparency from drug companies or a lack of price regulation as to why they can accumulate such significant profits without ceasing.

Imposing stricter price regulations and garnering compliance from pharmaceutical companies will continue to be a challenge as pharmaceutical companies are resistant to relinquishing their excess profits. Pharmaceutical companies have justified these high prices by explaining the resulting funds' necessity in funding future research projects for the innovation of new drugs, and when Congress tries to implement a changing of these prices, advocacy groups stand in the way claiming the possibility of missing a cure for diseases without the sufficient funds enabled by high drug prices to fuel further research [13].

Drug development companies also claim that the costs of failed projects must also be accounted for in regard to these high prices. Yet Hank McKinnell, a previous CEO of the pharmaceutical giant Pfizer, in his book A Call to Action claims that it is "the anticipated income stream, rather than repayment of sunk costs, that is the primary determinant of price" [13]. It appears that government regulation is one effective measure of reducing these high prices.

Yet problems with Congress and the resistance of pharmaceutical companies can stop this change dead in their tracks. Perspectives from former pharmaceutical executives illuminate that it is the efficacy of the drug and not the research costs that govern the price. This suggests that the high prices are enacted to strictly swell profits and not to only cover the costs of R&D. Through the use of cost-effective intervention measures and hopefully some more affordable drug pricing in the future, our world can finally get a grip on cancer and become better equipped to take on what it throws at us.

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